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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,342	01/30/2004	Hidetaka Arimura	235752US20	5232

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EXAMINER	
ABDI, AMARA	
ART UNIT	**PAPER NUMBER**
2609	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/09/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/09/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/767,342	ARIMURA ET AL.	
	Examiner	Art Unit	
	Amara Abdi	2609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-17* is/are rejected.

7)☐ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/21/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment received December 15th, 2005, has been acknowledged.

Specification

1. The specification is objected to because of the following informalities:

(1) Paragraph [0014], line 3, on page 6, "**the**" before "at least" should be deleted, the examiner suggest inserting "**the**" between "**at least**" and "**one**", the same informality was found **in paragraph [0016]**, line 3, **paragraph [0018]**, line 2, and paragraph [0019], line 4.

(2) Paragraph [0017], line 2, on page 7, "**[the]**" should be deleted.

(3) The statement regarding **federally sponsored research** should be inserted in the specification before the summary of the invention.

Appropriate correction is required.

Claim Objections

2. Claims 9-10 are objected to because of the following informalities:

(1) Claim 9, line 7, "**a** nodule contrast" should be changed to "**the** nodule contrast"

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The matched filter and ring-average filter was not described in the specification. Therefore the examiner will use the interpretation of each filter based on the definition in dictionary.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "**a matched filter**" in claim 4 is used by the claim to mean "to enhance the image", while the accepted meaning is "to compare favorably with". Also the term "**a ring-average filter**" in claim 4 is used by the claim to mean "to suppress the image", while the accepted meaning is "for **ring:** circular line, figure, or object, and for **average:** an estimation of". The term is indefinite because the specification does not clearly redefine the term.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claim 16 is rejected under U.S.C. 101 because the claimed invention is directed to non- statutory subject matter.

In claim 16, a "**computer program**" is being recited; however, computer program would reasonably be interpreted by one of ordinary skill in the art as software, pre se. This subject matter is not limited to that which falls within a statutory category of invention because it is limited to a process, machine, manufacture, or a composition of matter. Software is a function descriptive material and function descriptive material is non-statutory subject matter.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1,2,4,9-10,13-14,16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Xu et al. (US 6,141,437).

(1) Regarding claim 1,16 and 17:

As shown in figure 3, Xu et al. disclose a method for detecting at least one nodule in a medical image comprising (column 2, line 22-23):

identifying, in said medical image, an anatomical region corresponding to at least a portion of an organ of interest (column 7, line 4-6), (the examiner interpreted that the simplification of the normal anatomic background as the identification of anatomical region in medical image)

filtering said medical image to obtain a difference image (column 7, line 49-50)

detecting, in said difference image, a first plurality of nodule candidates within said anatomical region (figure 13(a)-13(d), column 7, line 6-8)

calculating respective nodule feature values of said first plurality of nodule candidates based on image pixel values of at least one of said medical image and said difference image (column 7, line 10-11)

removing false positive nodule candidates from said first plurality of nodule candidates based on said respective nodule feature values to obtain a second plurality of nodule candidates (column 7, line 12-15),

determining said at least one nodule by classifying each of said second plurality of nodule candidates as a nodule or a non-nodule based on at least one of said image pixel values and said respective nodule feature values (column 7, line 8-10).

(2) Regarding claim 2:

The method of claim 1, wherein the identifying step comprises:

forming a histogram of gray values of pixels in said medical image (column 3, line 6-8)

determining a gray-level threshold using said histogram (column 3, line 8-10)

identifying an outline of said anatomical region using said gray-level threshold (column 3, line 11-12)

(3) Regarding claim 4:

The method of claim 1, wherein the filtering step comprises:

filtering said medical image using a matched filter to obtain a nodule-enhanced image (column 7, line 52-55)

filtering said medical image using a ring-average filter to obtain a nodule-suppressed image (column 7, line 55-58),

subtracting said nodule-suppressed image from said nodule-enhanced image to obtain said difference image (column 7, line 60-62).

(4) Regarding claim 9:

The method of claim 1, wherein the calculating step comprises:

determining, for each candidate nodule in said first plurality of candidate nodules, at least one respective morphological feature value (column 2, line 41-41), including at least one of effective diameter, circularity, and irregularity (column 3, line 15-16)

determining, for each candidate nodule in said first plurality of candidate nodules, at least one respective gray level feature value, including at least one of a nodule contrast in said difference image, the nodule contrast in said medical image, the nodule contrast

of a nodule outer region, and a standard deviation of said nodule outer region (column 3, line 13-15).

(5) Regarding claim 10:

The method of claim 9, wherein the removing step comprises:

removing false positive nodule candidates from said first plurality of nodule candidates based on said at least one respective morphological feature (column 2, line 41-46) value and said at least one respective gray level feature value (column 2, line 37-41)

(6) Regarding claim 13:

The method of claim 1, wherein the determining step comprises:

determining said at least one nodule from said second plurality of nodule candidates based on said image pixel values using a Multi-MTANN (Massive Training Artificial Neural Network) (column 2, line 46-57), (the examiner interpreted the usage of Artificial Neural Network AAN as a multi massive training Artificial Neural Network MTANN, since it's using two hundred PA chest radiographs, (see the abstract))

(7) Regarding claim 14:

The method of claim 13, wherein the determining step comprises:

training a plurality of MTANNs to distinguish nodules from a respective type of non-nodules (column 7, line 13-15); and

classifying, based on said image pixel values, said second plurality of nodule candidates using said plurality of trained MTANNs to obtain said at least one nodule (column 7, line 8-10, and line 20-24).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. in view of Suzuki et al. (US 6,754,380)

Xu et al. disclose all the subject matter as in claim 1 above.

However, Xu et al. does not disclose the method for identifying, in a low-dose computed tomographic (LDCT) image, a lung region of the subject as recited in claim 3.

Suzuki et al. teaches a method of training massive training artificial neural network (MTANN) for the detection of abnormalities in medical images where a lung region of the subject were identified, in low-dose computed tomographic (LDCT) image (column 7, line 28-30).

One of ordinary skill in the art would have clearly recognized the usage of a low-dose computed tomographic (LDCT) image for identifying a lung region of the subject (Abstract, line 10-12, column 1, line 25-29). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to combine the system of Suzuki et al. where a lung region were identified by using a low-dose computed tomographic image in the system of Xu et al. because such feature may be applied to virtually any field in which a target pattern must be distinguished from other pattern in images. For example, it may be applied to those fields, in addition to the medical imaging application

such as: detection of traffic signals pedestrian, and other obstacles in road images, detection of eyes, mouth, and nose in facial image, detection of weather pattern structures such as rain, clouds, and thunderstorms, incipient tornadoes or hurricanes from satellite or high aircraft images. (Column 22, line 51-59, and column 23, line 5-8).

13. Claim 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. in view of Romsdahl et al. (USPGPUB 2002/0141627)

(1) Regarding claim 5:

Xu et al. disclose all the subject matter as in claim 1 above.

However, Xu et al. does not disclose a method, where the detecting step comprise the forming of initial regions within the anatomical region; selecting the first plurality of nodule candidate based on the initial region, where each nodule candidate have respective nodule region including on of the initial region; and determining the respective nodule region of each nodule candidate in the first plurality of nodule candidates using region growing as recited in claim 5.

Romsdahl et al. teach a system and method of density nodules detection in 3-D digital images where the initial regions within the anatomical region is formed (paragraph [0037], line 5-6), and the first plurality of nodule candidates are selected based on initial regions (paragraph [0037], line 3-5), and determining the respective nodule regions of each nodule candidate in the first plurality of nodule candidate using region growing (paragraph [0047], line 4-8).

One of ordinary skill in the art would have clearly recognized the forming of initial regions within the anatomical region (paragraph [0015], line 1-2), selecting the first plurality of nodule candidates based on the initial region (paragraph [0037], line 3-5), and determining the respective nodule regions of each nodule candidate in the first plurality of nodule candidate using region growing (paragraph [0047], line 5-6). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to combine the system of Romsdahl et al. where the initial regions were formed within the anatomical region in the system of Xu et al. because such feature provides a nodule detection process and system that is adaptable for a large range of anatomical regions for processing yet is fast enough to permit use of the CAD system in clinical radiology environment (paragraph [0017], line 14-18) as well as it has computational efficiency and accuracy of high priority to satisfy the throughput requirements of any digital processing method or system (paragraph [0016], line 8-10).

(2) Regarding claim 6:

Xu et al. further disclose the method, where the histogram of gray values of pixels is formed in the difference image (column 3, line 5-8); and determining the initial regions using multiple-gray-level thresholding of the histogram (column 3, line 8-12)

(3) Regarding claim 7:

Xu et al. further disclose the method for calculating respective effective diameter and circularity values for each of the initial regions (column 3, line 13-16), and selecting the first plurality of candidates nodules based on the respective effective diameter and circularity values of each of the initial regions (column 3, line 18-24)

14. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. in view of Doi et al. (USPGPUB 2002/0172403)

(1) Regarding claim 11:

Xu et al. disclose all the subject matter as in claim 1 above.

However, Xu et al. does not disclose the method for determining at least one interior and an exterior feature value, for each candidate nodule, including one of an average pixel value, full width at half maximum (FWHM), and full width at tenth maximum (FWTH), based on pixel values in the interior and exterior region of each candidate nodule as recited in claim 11.

Doi et al. teach a an automated method for analyzing a nodule, where the calculating step include determining the interior feature value and exterior feature value for each nodule candidate, including one the average pixel value, full width at half maximum (FWHM), and full width tenth maximum (FWTM), bases on pixel values in the interior and exterior region of nodule candidate (paragraph [0069], line 4-9)

One of ordinary skill in the art would have clearly recognized the determining of the interior and exterior feature value for each nodule candidate based on pixel values on the interior and exterior region of nodule candidate (paragraph [0069], line 1-9). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to combine the system of Doi et al. for analyzing a nodule in the system of Xu et al. because such feature provides the analysis of the likelihood of malignancy in solitary pulmonary nodules on chest images, where manual identification of nodules is avoided or simplified (paragraph [0032], line 2-4), as well as such feature have CT

derived feature that will enable the identification of the substantial percentage of non-malignant tumors, by which the avoidance of biopsy or additional imaging can be avoided (paragraph [0099], line 5-8)

(2) Regarding claim 12:

Xu et al. further disclose the method, where the removing of false positive nodules candidates from the first plurality of nodule candidates (column 7, line 12-15), is based on at least one respective interior feature value (column 7, line 31-33), at least one exterior feature value, and the location of the nodule candidates within the anatomical region (column 7, line 4-6), (the examiner interpreted the normal anatomic background as the anatomical region)

15. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. in view of Reeves et al. (PGPUB 2003/0095696)

(1) Regarding claim 15:

Xu et al. disclose all the subject matter as in claim 1 above.

However, Xu et al. does not disclose a method, where the determining step of at least one nodule from the second plurality of nodule candidates using a linear discriminant analysis, based on the respective feature values as recited in claim 15.

Reeves et al. teach system, method and apparatus for small pulmonary nodule computer aided diagnosis from computed tomography scans, where at least one nodule from the second plurality of nodule candidates is determined using a linear discriminant analysis, based on nodule feature values (paragraph [0006], line 3-4).

One of ordinary skill in the art would have clearly recognized the determining of at least one nodule from the plurality of nodule candidates based on nodule feature values, using a linear discriminant analysis (paragraph [0107], line 7-8). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to combine the method of Reeves et al. where at least one nodule is determined from plurality of nodule candidates using a linear discriminant analysis in the system of Xu et al. because such feature focuses in the analysis of small pulmonary nodules that are less than 1 centimeter, as well as it's also suitable for larger nodules analysis (paragraph [0010], line 12-15), so it's very accurate method for determining a nodule features either for big or small nodules.

Allowable Subject Matter

16. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

17. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record Xu et al. and Romsdahl et al. does not teach or suggest determining the nodule region of each candidate based on respective differences between the first morphological image feature and the second morphological images feature.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kaufman et al. (USPGPUB 2003/0028401) disclose a method, database, and software code for generating a customizable body report.

Ginger et al. (USPGPUB 2004/0101181) disclose an automated method for determining prognosis based on an analysis of abnormality (lesion) feature obtain from a medical image data of a patient.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amara Abdi whose telephone number is (571) 270-1670. The examiner can normally be reached on Monday through Friday 7:30 Am to 5:00 PM E.T..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shuwang Liu can be reached on (571) 272-3036. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amara Abdi
02/21/2007

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SUPERVISORY PATENT EXAMINER